

**REMARKS**

Claims 17 to 38 are pending.

Applicants respectfully request reconsideration of the present application in view of this response.

Applicants thank the Examiner for acknowledging the claim for foreign priority and for indicating that all certified copies of the priority documents have been received.

Applicants thank the Examiner for considering the previously filed Information Disclosure Statement, PTO 1449 paper and cited references.

The drawings were objected to under 37 CFR 1.83(a).

In particular, the Office Action asserts that the drawings do not include structural details necessary to understand the claimed subject matter. However, the Office Action does not point to any specific structural elements missing from the drawings. In this regard, it is noted that 37 CFR 1.83(a) only requires that the drawings show every feature *specified in the claims*. It is respectfully submitted that the Office Action's assertions simply do not identify what claimed features are missing from the drawings. Also, the requirements of Rule 83(a) relate only to the subject matter specified in the claims – and not the specification (as asserted).

As further regards the objections, 37 C.F.R. § 1.83(a) (“Rule 83(a)”) is subject to 37 C.F.R. § 1.81 -- *which only requires a drawing “where necessary for the understanding of the subject matter sought to be patented”*. The Office Action has not addressed this fact. In view of the claims, the specification disclosure, and the other Figures, it is respectfully submitted that no other drawing is necessary for understanding the claimed subject matter which is fully described by the specification (including the present drawings) and/or the claim itself.

It is therefore respectfully submitted that the drawings satisfy the requirements of 37 CFR 1.83(a). Accordingly, it is respectfully submitted that the drawings objections be withdrawn.

Claims 17 to 38 were rejected under 35 U.S.C. § 112, first paragraph, as to the written description and enablement requirements.

It is respectfully submitted that the Office Action's arguments and assertions simply do not identify why the rejected claims are not supported by the written description of the present application (and its specification) — which it plainly is, as explained herein. In this regard, the Office Action does not explain why a person skilled in the art would not recognize the various features of the claims (including as a grammatical matter). The present application makes this plain to any person having ordinary skill (or any person for that matter).

As stated by the Board in Ex parte Harvey, 3 U.S.P.Q. 2d 1626, 1627 (Bd. Pat. App. Int. 1986) (emphasis added, citations omitted):

**Compliance with the written description requirement of Section 112 only requires that appellant's application contain sufficient disclosure, *expressly or inherently*, to make it clear to persons skilled in the art that appellant possessed the subject matter claimed. The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession of the claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language.**

Likewise, as stated by the Board in Ex parte Sorenson, 3 U.S.P.Q. 2d 1462, 1463 (Bd. Pat. App. Int. 1987) (emphasis added):

**[W]e are mindful that appellant's specification need not describe the claimed invention in *ipsis verbis* to comply with the written description requirement. The test is whether the originally filed specification disclosure reasonably conveys to a person having ordinary skill that applicant had possession of the subject matter later claimed. . . . Moreover, the Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in appellant's specification disclosure a description of the invention defined by the claims.**

In particular, the Sorenson Board, noting that the examiner only essentially stated that the claim expressions at issue did not “appear in the original disclosure” and that the claim expressions were therefore “not adequately supported by the few specific compounds in the specification”, found that the examiner had not met his initial burden of “presenting evidence why a person having ordinary skill in the art would not recognize in appellant's specification a description of the invention defined by the claims” — and that the “only reasoning

presented” that the Board could discern was an “example of *ipse dixit* reasoning, resting on a bare assertion by the Examiner”.

It is therefore respectfully submitted that the present application does satisfy the written description requirement of 35 U.S.C. § 112. Accordingly, it is respectfully submitted that the “written description” rejection of the claims should be reversed.

As to the enablement rejections, it is respectfully submitted that the assertions and arguments of the Office Actions do not fully reflect the standard for determining whether a patent application complies with the enablement requirement that the specification describe how to make and use the invention -- which is defined by the claims. (See M.P.E.P. § 2164). The Supreme Court established the appropriate standard as whether any experimentation for practicing the invention was undue or unreasonable. (See M.P.E.P. § 2164.01 (citing Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916); In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed Cir. 1988))). Thus, it is axiomatic that the enablement test is “whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” (See id. (citing United States v. Teletronics, Inc., 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988))).

The Federal Circuit has made clear that there are many factors to be considered in determining whether a specification satisfies the enablement requirement, and that these factors include but are not limited to the following: the breadth of the claims; the nature of the invention; the state of the prior art; the level of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the disclosure. (See id. (citing In re Wands, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404 and 1407)). In this regard, the Federal Circuit has also stated that it is “improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors,” and that the examiner’s analysis must therefore “consider all the evidence related to each of these factors” so that any non-enablement conclusion “must be based on the evidence as a whole.” (See M.P.E.P. § 2164.01).

Also, an examiner bears the initial burden of establishing why the “scope of protection provided by a claim is not adequately enabled by the disclosure.” (See id. (citing In re Wright, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993))).

Accordingly, a specification that teaches the manner and process of making and using an invention in terms that correspond in scope to those used in describing and defining the claimed subject matter complies with the enablement requirement. (See *id.*).

In contrast to the above, however, it is respectfully submitted that the assertions to date do not concern — as they must under the law — whether the present application enables a person having ordinary skill in the art to practice the claimed subject matter of the claims without undue experimentation — which it plainly does, as would be understood by a person having ordinary skill in the art in view of the disclosure of the present application, including the specification — and as explained above. In short, the assertions to date are essentially conclusory and still do not adequately address the issue of whether one having ordinary skill would have to unduly experiment to practice the claimed subject matter of the rejected claims — a proposition for which the Office bears the burden of proving a *prima facie* case as to the rejected claims.

In this regard, to properly establish enablement or non-enablement, the Office must make use of proper evidence, sound scientific reasoning and the established law. In the case of *Ex Parte Reese*, 40 U.S.P.Q.2d 1221 (Bd. Pat. App. & Int. 1996), a patent examiner rejected (under the first paragraph of section 112) application claims because they were based on an assertedly non-enabling disclosure, and was promptly reversed because the rejection was based only on the examiner's subjective belief that the specification was not enabling as to the claims. In particular, the examiner's subjective belief was simply not supported by any “evidence or sound scientific reasoning” and therefore ignored recent case law — which makes plain that an examiner (and not an applicant) bears the burden of persuasion on an enablement rejection.

More particularly, the examiner in *Ex parte Reese* was reversed because the rejection had only been based on a conclusory statement that the specification did not contain a sufficiently explicit disclosure to enable a person to practice the claimed invention without exercising undue experimentation — which the Board found to be merely a conclusory statement that only reflected the subjective and unsupported beliefs of a particular examiner and that was not supported by any proper evidence, facts or scientific reasoning. (See *id.*). Moreover, the Board made clear that it is “incumbent upon the Patent Office . . . to back up assertions of its own with acceptable evidence,” and also made clear that “[where an] examiner's 'Response to Argument' is not supported by evidence, facts or sound scientific

reasoning, [then an] examiner has not established a *prima facie* case of lack of enablement under 35 U.S.C. § 112, first paragraph.” (See *id.* at 1222 & 1223; italics in original).

In the present case, it is respectfully submitted that the Office Action has not satisfied the foregoing for establishing that undue experimentation would be required, and it is therefore respectfully requested that the enablement rejections as to claims 17 to 38 be withdrawn for all of the above reasons.

Accordingly, claims 17 to 38 are allowable.

**CONCLUSION**

It is therefore respectfully submitted that claims 17 to 38 are allowable. It is therefore respectfully requested that the rejections (and any objections) be withdrawn, since all issues raised have been addressed and obviated. An early and favorable action on the merits is therefore respectfully requested.

Respectfully submitted,

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